



Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of headache.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of headache. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jan. 70 p. [121 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Diagnosis and treatment of headache. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 68 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, the U.S. Food and Drug Administration (FDA) asked manufacturers of non-prescription (over the counter [OTC]) non-steroidal anti-inflammatory drugs (NSAIDs) to revise their labeling to include more specific information about potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drugs. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all NSAIDs make labeling changes to their products. FDA recommended proposed labeling for both the prescription and OTC NSAIDs and a medication guide for the entire class of prescription products. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
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IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Headache including

- Migraine headache (including hormone-related migraine [menstrual-associated, perimenopausal/menopausal, on estrogen-containing contraceptives migraine headache])
- Tension-type headache
- Cluster headache

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Neurology
Obstetrics and Gynecology
Pediatrics
Pharmacology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the accurate diagnosis and treatment of headaches
- To increase the functional status of those with migraine
- To increase the rate of treatment plans or adherence to plan for mild, moderate, and severe headaches for migraine sufferers
- To reduce the use of narcotics and barbiturates for the treatment of primary headache
- To increase education for primary headache sufferers
- To increase appropriate prophylactic treatment based on headache type (e.g., migraine, tension-type, cluster, and menstrual-associated migraine headache)
- To increase appropriate acute and prophylactic treatment for migraine sufferers based on level of severity (e.g., mild, moderate, or severe migraine)

TARGET POPULATION

Patients age 12 years and older who present with headache

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Detailed history of headaches (e.g., characteristics; severity; precipitating, aggravating, and relieving factors)
2. Focused physical examination
3. Focused neurological examination
4. Evaluation of causes for concern
5. Selective diagnostic testing including neuroimaging (computed tomography [CT] or magnetic resonance imaging [MRI]), electroencephalogram, lumbar puncture, cerebrospinal fluid, and blood studies, as indicated
6. Specialty consultation as indicated
7. Evaluation of stroke risk for patients with migraines with auras on estrogen-containing contraceptives

Management/Treatment/Prevention

See individual algorithms and the Drug Treatment and Prophylactic Treatment Tables in Annotation Appendixes A and B in the original guideline document for more information.

1. Patient education and lifestyle management
2. Specialty referral as indicated

Migraine Treatment

1. Over the counter (OTC) medications, including aspirin and nonsteroidal anti-inflammatory drugs (NSAIDS)
2. Triptans
3. Adjunctive therapy, including caffeine and metoclopramide
4. Intravenous (IV) dihydroergotamine (DHE) with metoclopramide for nausea
5. Chlorpromazine, valproate sodium IV, magnesium sulfate IV, or prochlorperazine
6. Dexamethasone

7. Ketorolac and opiates were considered but are not recommended as drugs of first choice

Tension Headache

1. Acute treatment with analgesics, such as acetaminophen and NSAIDS
2. Prophylactic treatment, including tricyclic antidepressants

Note: See Tension-Type Headache Algorithm and "Drug Treatment Tables" in Annotation Appendix A in the original guideline document for more information about treatment.

Cluster Headache

1. Acute treatment, including oxygen inhalation, subcutaneous sumatriptan, and DHE
2. Prophylactic treatment through maintenance therapy

Menstrual-Associated Migraine

1. Cyclic prophylaxis (NSAIDS, triptans, ergots)
2. Hormonal prophylaxis (estradiol patches, estrogen-containing contraceptives, gonadotropin-releasing hormone [GnRH] agonists)

Migraine Prophylaxis

1. First-line treatment (including tricyclic antidepressants and sodium valproate) based on individual considerations
2. Other therapies, including acupuncture, biofeedback, botulism toxin A, butterbur root, cognitive behavioral therapy, feverfew, magnesium, relaxation training, and riboflavin

MAJOR OUTCOMES CONSIDERED

- Accuracy of diagnostic assessments and diagnostic yield
- Functional status and quality of life
- Degree of headache relief
- Headache frequency and severity
- Migraine symptoms (nausea, vomiting, vision disturbances)
- Need for analgesic medication
- Risk of stroke with oral contraceptive use
- Safety, cost, and side effects of medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Diagnostic Testing

In a retrospective study, 592 patients with headaches and normal neurological exam were examined by computed tomography (CT) scanning between 1990 and 1993 at a cost of \$1,000 per scan. None of the patients had any serious intracranial pathology identified. This technique is costly and unrewarding.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are

developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Committee on Evidence-Based Practice carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Committee on Evidence-Based Practice reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to "[Summary of Changes -- January - 2006](#)."

The recommendations for the management of migraine headaches are presented in the form of 10 algorithms with 153 components, accompanied by detailed annotations. In addition to a [Main algorithm](#), algorithms are provided for: [Diagnosis](#); [Migraine Treatment](#); [Tension-Type Headache](#); [Cluster Headache](#); [DHE \(Dihydroergotamine Mesylate\)](#); [Menstrual-Associated Migraine](#); [Perimenopausal or Menopausal Migraine](#); [On Estrogen-Containing Contraceptives or Considering](#)

[Estrogen-Containing Contraceptives with Migraine](#); [Migraine Prophylactic Treatment](#). Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Headache is diagnosed by history and physical examination with limited need for imaging or laboratory tests. (Annotation #11)
2. Warning signs of possible disorder other than primary headache are: (Annotation #12)
 - Subacute and/or progressive headaches which worsen over time (months)
 - A new or different headache
 - Any headache of maximum severity at onset
 - Headache of new onset after age 50
 - Persistent headache precipitated by a Valsalva maneuver
 - Evidence such as fever, hypertension myalgias, weight loss, or scalp tenderness suggesting a systemic disorder
 - Presence of neurological signs that may suggest a secondary cause
 - Seizures
3. Appropriate pharmacological or analgesic treatment of acute headache should generally not exceed more than 2 days per week on a regular basis. More treatment other than this may result in chronic daily headaches. (Annotations # 16, 30)
4. Migraine-associated symptoms are often misdiagnosed as "sinus headache" by patients and providers. This has led to the underdiagnosis and treatment of migraine. (Annotation #16)
5. Most medications should be started in a low dose and titrated to a therapeutic dose to minimize side effects and maintained at target dose for 8-12 weeks to obtain maximum efficacy. (Annotation # 144)
6. Migraines occurring in association with menses and not responsive to standard cyclic prophylaxis may respond to hormonal prophylaxis with use of estradiol patches or estrogen-containing contraceptives. (Annotation # 101)
7. Women who have migraines with aura should avoid use of estrogen-containing contraceptives. Headaches occurring during perimenopause or after menopause may respond to hormonal therapy. (Annotation # 117)
8. Disability from headaches is an important issue for migraineurs. (Annotation # 30)
9. All patients should be considered for prophylactic therapy. (Annotations #55, 63, 110, 113; see the original guideline document for annotations #55 and 63)

Diagnosis Algorithm Annotations

10. Patient Presents with Complaint of a Headache

A patient may present for care of headaches during an attack or during a headache-free period. If a patient presents during a headache, appropriate evaluation (history, examination, appropriate testing) needs to be undertaken

in a timely fashion. Once the diagnosis of primary headache is established, acute treatment is instituted. If the patient has a history of recurrent headaches, a plan for treatment (acute and prophylactic) needs to be established.

11. Critical First Steps

Key Points:

- Headache is one of the most frequent diseases seen in clinics by health care providers.
- Minimal general physical examination is performed at the first consultation of patient presenting with a headache.

Headache can be diagnosed by symptoms and signs with the use of biologically based International Headache Society (IHS) criteria. The IHS system presently provides the gold standard. As empirical evidence and clinical experience accumulates criteria for diagnosing headaches will be revised.

Detailed History

Functional disabilities at work, school, housework, or leisure activities during the past 3 months (informally or using well-validated disability questionnaire).

Assessment of the headache characteristics requires determination of the following:

Temporal profile:

- Time from onset to peak
- Usual time of onset (season, month, menstrual cycle, week, hour of day)
- Frequency and duration
- Stable or changing over past 6 months and lifetime

Autonomic features:

- Nasal stuffiness
- Rhinorrhea
- Tearing
- Eyelid ptosis or edema

Descriptive Characteristics: pulsatile, throbbing, pressing, sharp, etc.

Location: uni- or bilateral, changing sides

Severity

Precipitating features and factors which aggravate and/or relieve the headache

Factors which relieve the headache

History of other medical problems

Pharmacological and non-pharmacological treatments which are effective or ineffective
Aura (present in approximately 15% of migraine patients)

Focused Physical Exam

Vital signs (blood pressure, pulse, respirations, and temperature)
Extracranial structure evaluation such as carotid arteries, sinuses, scalp arteries, cervical paraspinal muscles
Examination of the neck in flexion versus lateral rotation for meningeal irritation. (Even a subtle limitation of neck flexion may be considered an abnormality.)

Focused Neurological Examination

A focused neurological examination may be capable of detecting most of the abnormal signs likely to occur in patients with headache due to acquired disease or a secondary headache.

This exam should include at least the following evaluations:

- Assessment of patient's awareness and consciousness, presence of confusion, and memory impairment
- Ophthalmological exam to include pupillary symmetry and reactivity, optic fundi, visual fields, and ocular motility
- Cranial nerve examination to include corneal reflexes, facial sensation, and facial symmetry
- Symmetric muscle tone, strength (may be as subtle as arm or leg drift), or deep tendon reflexes
- Sensation
- Plantar response(s)
- Gait, arm and leg coordination

Headache is one of the most frequent diseases seen in clinics by health care providers.

Minimal general physical examination is performed at the first consultation of patient presenting with a headache.

12. Causes for Concern?

Causes for concern must be evaluated irrespective of the patient's past history of headache. Warning signs of possible disorder other than primary headache are:

- Subacute and/or progressive headaches which worsen over time (months)
- A new or different headache or a statement by a headache patient that "this is the worst headache ever"
- Any headache of maximum severity at onset
- Headaches of new onset after the age of 50 years old

- Persistent headache precipitated by a Valsalva maneuver such as cough, sneeze, bending, or with exertion (physical or sexual)
- Evidence such as fever, hypertension, myalgias, weight loss, or scalp tenderness suggesting a systemic disorder
- Neurological signs that may suggest a secondary cause. For example, meningismus, confusion, altered levels of consciousness, changes or impairment of memory, papilledema, visual field defect, cranial nerve asymmetry, extremity drifts or weaknesses, clear sensory deficits, reflex asymmetry, extensor plantar response, or gait disturbances.
- Seizures

Evidence supporting this recommendation is of class: R

13. Consider Secondary Headache Disorder

The presence of the symptoms or signs listed above suggests a secondary cause for the headache, and could be indicative of an underlying organic condition. Alternate diagnoses include subarachnoid hemorrhage, tumor, meningitis, encephalitis, temporal arteritis, idiopathic intracranial hypertension, and cerebral venous thrombosis, among others.

Secondary Headaches

- Subacute and/or progressive, worsening headaches over weeks to months:

Headaches that worsen with time may be due to a progressive intracranial lesion such as tumor, subdural hematoma, or hydrocephalus. While the neurologic examination may reveal abnormalities that suggest a sinister process, this is not always the case. Accordingly, a history of a progressive headache is an indication for head imaging. For most processes, magnetic resonance imaging (MRI) with and without gadolinium contrast will be more sensitive than a computed tomography (CT) head scan.

- A new or different headache or a statement by a headache patient that "this is the worst headache of my life":

Primary headache disorders (mainly tension-type headache and migraine) are exceedingly common. A history of a primary headache disorder does not confer protection against a new, serious process that presents with headache. The acuteness of a headache will largely define the differential diagnosis. Headache that presents suddenly, "like a thunderclap" can be characteristic of several serious intracranial processes, including subarachnoid hemorrhage (SAH), venous sinus thrombosis, bacterial meningitis, spontaneous cerebrospinal fluid (CSF) leak, carotid dissection, and rarely, pituitary apoplexy and hypertensive encephalopathy. The first investigation is a CT head scan without contrast. If there is no evidence of a SAH, a lumbar puncture should be performed. If both studies are normal an MRI with and without gadolinium should be obtained. Consideration of magnetic

resonance angiography (MRA) and magnetic resonance venography (MRV) should be given although consultation is indicated as well.

If the headache is more subacute in onset, chronic meningitis may need to be considered along with a space occupying intracranial lesion or hydrocephalus. Again, neuroimaging should be performed. Whether a lumbar puncture (LP) is done will be guided by the index of suspicion regarding a meningeal process (e.g., meningitis).

- Headache of sudden onset:

This refers mainly to thunderclap headache (see above). It should be treated as an emergency since the possible presence of aneurysmal subarachnoid hemorrhage needs to be assessed as outlined above. Other secondary causes of headache will be found less commonly.

- Headache precipitated by a Valsalva maneuver such as cough, sneeze, bending, or with exertion:

Valsalva headaches, while often representing primary cough headache, can signal an intracranial abnormality, usually of the posterior fossa. The most commonly found lesion is a Chiari malformation although other posterior fossa lesions are sometimes found. Less commonly there are intracranial lesions located elsewhere. An MRI needs to be obtained to appropriately investigate for these possibilities. Exertional headache, such as with exercise or during sexual activity, may represent a benign process such as migraine. However, if the headache is severe or thunderclap in onset, investigations will be necessary as already outlined above.

- Headaches of new onset after the age of 50 years:

The large majority of individuals who are destined to develop a primary headache disorder do so prior to age 40 years. Of course, this is not universal and migraine or other primary headache disorders may begin even at an advanced age. Nevertheless, care should be taken before a diagnosis of a primary headache disorder is assigned. Many patients who do have the onset of a new headache disorder after age 40 years will merit brain imaging. In addition, after the age of 50 years, a new headache disorder should evoke suspicion of possible giant cell arteritis. Obviously, symptoms of polymyalgia rheumatica, jaw claudication, scalp tenderness, or fever will increase the likelihood of this diagnosis. Findings of firm, nodular temporal arteries and decreased temporal pulses will increase the suspicion as will an elevated sedimentation rate.

- Symptoms suggestive of a systemic disorder such as fever, myalgias, weight loss, or scalp tenderness or a known systemic disorder such as cancer or immune deficiency:

Systemic disorders, while not incompatible with a coexistent primary headache disorder, should signal caution. Patients should be carefully evaluated. Obviously, the differential diagnosis will be long and the index of suspicion for any given process will largely depend on the clinical setting.

- Presence of subtle neurological signs suggests a secondary cause for headache. For example, meningismus, confusion, altered level of consciousness, memory impairment, papilledema, visual field defect, cranial nerve abnormalities, pronator drift, extremity weakness, significant sensory deficits, reflex asymmetry, extensor plantar response, or gait disturbance when accompanying a headache should elicit caution:

While neurological signs may be unrelated to a headache, previously undocumented neurological findings that are presumably new need to be carefully considered. Usually cranial imaging will be the initial study. Depending on the index of suspicion, lumbar puncture and blood studies may be indicated.

- Seizures:

While seizures can occasionally be a manifestation of a primary headache disorder such as migraine, this is the exception and not the rule; it is a diagnosis of exclusion. Other etiologies for seizures including space occupying lesions, infection, stroke, and metabolic derangements will need to be considered. Again, MRI is the imaging procedure of choice unless there is an issue of acute head trauma, in which case a CT head scan should be obtained initially.

- Diagnosis to be included in secondary headache:
 - Subdural hematoma
 - Epidural hematoma
 - Tumor
 - Chiari malformation
 - Toxins (e.g., carbon monoxide)
 - Giant cell arteritis
 - Acute hydrocephalus
 - Obstructive hydrocephalus
 - Other metabolic disorders
 - Infectious causes:
 - meningitis
 - encephalitis
 - abscess

14. Meets Criteria for Primary Headache Disorder?

The IHS criteria for migraine have been studied in a community population sample without consideration of treatment. Findings suggest that the best criteria differentiating migraine from other headache types are the presence

of nausea and/or vomiting in combination with two of the following three symptoms: photophobia, phonophobia, and osmophobia.

See table titled "Modified Diagnostic Criteria" in the original guideline document, which has been modified from the IHS criteria, and describes the differentiating criteria applicable for the diagnosis of migraine and other primary headache disorders.

16. Evaluate Type of Primary Headache/Initiate Patient Education and Lifestyle Management

Migraine-associated symptoms are often misdiagnosed as "sinus headache" by patients and providers. This has led to the underdiagnosis and treatment of migraine.

While education is of paramount importance in managing any condition, it is especially important in the ongoing management of headache. Patients may have to make lifestyle changes and are often required to make self-management choices in the treatment of individual headaches, and should maintain a diary to clarify the frequency, severity, triggers, and treatment responses of their headaches. Refer to the original guideline document for detailed information regarding type of headache, lifestyle changes, and self-management.

Evidence supporting this recommendation is of classes: A, B, D

21. Specialty Consultation Indicated?

The decision to seek a specialty consultation will depend upon the practitioner's familiarity and comfort with headache and its management. Specialty consultation may be considered when:

- The diagnosis cannot be confirmed.
- Etiology cannot be diagnosed or warning signals are present.
- Headache attacks are occurring with a frequency or duration sufficient to impair the patient's quality of life despite treatment or the patient has failed to respond to acute remedies or is in status migrainosus.

22. Perform Diagnostic Testing if Indicated

Key Points:

- The diagnosis of primary headache is dependant on the experience of the clinician. There are, as of yet, no tests which confirm the diagnosis of primary headache.
- A detailed headache history, including duration of attacks and the exclusion of secondary causes is the primary means to diagnosis primary headache.

There are, as yet, no tests which confirm the diagnosis of primary headache. Selective testing, including neuroimaging (CT or MRI), electroencephalogram,

lumbar puncture, cerebrospinal fluid and blood studies, may be indicated to evaluate for secondary headache if causes of concern have been identified in the patient history or physical examination (see Annotation #12, "Causes for Concern?"). Diagnosis may be complicated if several headache types coexist in the same patient.

Evidence supporting this recommendation is of classes: C, M, R

Migraine Treatment Algorithm Annotations

27. Patient Meets Criteria for Migraine

Migraine is the most common headache disorder seen by primary care providers.

It is expected that a patient with headache undergo a diagnostic work-up (see the [Diagnosis Algorithm](#)) establishing the diagnosis of migraine before initiating acute treatment.

28. Is Patient Experiencing a Typical Headache?

Key Points:

- The diagnosis of migraine does not exclude the presence of an underlying secondary cause of headache.

Each individual headache must be evaluated in the context of the patient's prior migraine headaches. The practitioner must always remain alert to the possibility of secondary causes for headache, particularly when there is a previously established history of a primary headache disorder such as migraine.

Migraine does not preclude the presence of underlying pathology (arterial dissection, intracranial aneurysm, venous sinus thrombosis, ischemic or hemorrhagic stroke, temporal arteritis, etc.) which may also present with "vascular headaches." If the history is scrutinized, ominous causes for headaches can often be identified and treated with the potential to avoid catastrophe.

30. Categorize According to Peak Severity Based on Functional Impairment, Duration of Symptoms, and Time to Peak Impairment

Accurate categorization and characterization by both providers and patients is important. The categorization of migraine influences choice of treatment method.

Severity levels:

Mild - Patient is aware of a headache but is able to continue daily routine with minimal alteration.

Moderate - The headache inhibits daily activities but is not incapacitating.

Severe - The headache is incapacitating.

Status - A severe headache that has lasted more than 72 hours.

There may be additional features that influence choice of treatment. For example, parenteral administration (subcutaneous, nasal) should strongly be considered for people whose time to peak disability is less than 1 hour, who awaken with headache, and for those with severe nausea and vomiting.

Determining functional limitations during migraine episodes may be the key to determining the severity and therefore the best treatment for a patient. Physicians and patients should stratify treatment based on severity rather than using stepped care, though patients will often use stepped care within an attack. This algorithm uses a stratified-care model.

Factors that May Trigger Migraine

Certain influences can lead to a migraine attack. It is important to note that although a single trigger may provoke the onset of a migraine, a combination of factors is much more likely to set off an attack.

Refer to the original guideline document for a detailed list of triggers, including environmental triggers, lifestyle habits, hormonal triggers, emotional triggers, medications, and dietary triggers.

32. Mild Treatment

Key Points:

- Mild migraines are usually managed by the patient which implies an emphasis on over-the-counter (OTC) medications.
- Triptans are more effective at halting migraine pain at mild levels than if the headache is more severe.

The guideline work group presumes most mild migraine headaches will be managed by self-care, which implies an emphasis on over-the-counter (OTC) medications. However, since only 2 to 12% of initially mild migraine episodes remain mild (with the remainder progressing), treatments effective for mild headaches may be useful for only a short time. Studies on treatment of migraine headache at the mild level show that triptans are more effective in abolishing pain at this stage than if the headache is more severe. It is acceptable to use other symptomatic headache relief drugs as well as triptans for mild headache. However, current retrospective analyses of mild pain treatment studies reveal triptan response to 2-hour pain freedom to be superior to any other comparator drug. Please see Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Use of drugs for acute treatment of headache for more than 9 days per month is associated with an increased risk of chronic daily headache.

See Annotation Appendix C, "FDA Risk Factors for Drug Treatment in Pregnant Women" in the original guideline document.

Evidence supporting this recommendation is of classes: A, C, D, M, R

33. Successful?

Success for treatment of migraine is defined as complete pain relief and return to normal function within two hours of taking medication. In addition, patients should not have intolerable side effects and should find their medications reliable enough to plan daily activities despite migraine headache.

Consider reasons for treatment failure and change treatment plan.

Common reasons for migraine treatment failure are provided in the original guideline document.

Evidence supporting this recommendation is of class: R

36. Moderate Treatment

The guideline emphasizes the use of other agents over opiates and barbiturates, recognizing that many migraineurs are currently treated with drugs from the latter two classes. In general, opiates are characterized by having a short pain-relief window, release inflammatory neurochemicals, and increase vasodilation none of which address the currently known treatment issues and pathophysiology of migraine.

Meperidine (Demerol®) is commonly prescribed but its use should be avoided. The metabolite of meperidine, normeperidine, has a long half-life, produces less analgesic effect, and there is an increased risk of seizures that cannot be reversed by naloxone (Narcan®)

If an opiate must be used, meperidine should not be the opiate selected. The guideline developers have specifically excluded butorphanol because of its high potential for abuse and adverse side effect profile.

See Annotation Appendix C, "FDA Risk Factors for Drug Treatment in Pregnant Women" in the original guideline document.

43. Status (>72 Hour Duration)

It is recommended that the patient be hydrated prior to neuroleptic administration with 250 to 500 mL of 5% dextrose with 0.45% NaCl, and advised of the potential for orthostatic hypotension and acute extrapyramidal side effects. The patient should be observed in a medical setting as clinically appropriate after administration of a neuroleptic and should not drive for 24 hours.

44. Adjunctive Therapy

See "Drug Treatment for Adjunctive Therapy" table, Annotation Appendix A in the original guideline document. As adjunctive therapy, any of the listed medications can be used singularly or in compatible combination. For intermittent, infrequent headache, caffeine should be added as first choice when not contraindicated. The use of caffeine in patients with chronic daily headache is to be discouraged. The prokinetic agent metoclopramide could be considered next. This guideline has no other preferences.

45. Patient Meets Criteria for Dihydroergotamine (DHE)?

Key Points:

- DHE is effective in halting intractable migraine attacks or migraine status. DHE is also effective in halting the acute cycle of cluster headaches.

DHE must not be given to patients with the following conditions:

- Pregnancy
- History of ischemic heart disease
- History of variant angina
- Severe peripheral vascular disease
- Onset of chest pain following administration of test dose
- Within 24 hours of receiving any triptan or ergot derivative
- Patients with hemiplegic or basilar-type migraine

Intravenous DHE is the method most frequently employed to terminate a truly intractable migraine attack or migraine status. The protocol outlined in the DHE algorithm is effective in eliminating an intractable migraine headache in up to 90% of patients within 48 hours. This method of administration has also been found to be effective in terminating an acute cycle of cluster headaches as well as chronic daily headaches with or without analgesic/ergotamine rebound.

47. Chlorpromazine, Valproate Sodium Intravenous (IV), Magnesium Sulfate IV or Prochlorperazine

See the "Status Therapy" table, Annotation Appendix A, "Drug Treatment Tables." in the original guideline document. Patient with a history of dystonic reaction should be premedicated with diphenhydramine or benztropine (Cogentin).

If chlorpromazine, valproate sodium (Depacon), or magnesium sulfate IV were used previously, one may not wish to repeat.

Evidence supporting this recommendation is of class: A, C, D

49. Ketorolac or Opiates

These are not drugs of first choice and headache practice recommends against the use of meperidine. Normeperidine, the active metabolite of

meperidine has a long half-life and is neuroexcitatory and neurotoxic. There is inconsistent absorption of opiates, at least with meperidine, which when injected intramuscularly has less opioid effect than when given intravenously. Opiates release inflammatory neurochemicals and increase vasodilation that are mechanistically counter-productive to currently known migraine pathophysiology and can exacerbate headaches. Studies have been done using meperidine but the effects are likely due to class effect and other opiates are likely to be just as effective. However, it should be noted that there are no studies to support opiate effectiveness.

See the Status Therapy table, Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Evidence supporting this recommendation is of class: C

51. Dexamethasone

See the Status Therapy table, Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Evidence supporting this recommendation is of class: C

Tension-Type Headache Algorithm Annotations

59. Patient Meets Criteria for Tension-Type Headache?

Tension-type headache is one of the most common primary headaches. See Annotation #14 for episodic and chronic tension-type headache.

It is important to evaluate the patient that comes to the office for tension-type headache for the possibility of migraine. While the IHS system suggests migraine and tension-type headaches are distinct disorders, there is evidence to suggest that for the migraineur, tension-type headache is actually a low-intensity migraine.

62. Acute Treatment

Analgesics offer a simple and immediate relief for tension-type headache. Medication overuse is potentially a concern that can lead to chronic daily headache. Use of drugs for acute treatment of headache for more than 9 days per month is associated with an increased risk of chronic daily headache.

See Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

66. Prophylactic Treatment

Prophylactic therapy is reserved for patients with frequent tension-type headache (more than 15 headaches per month).

Tricyclic antidepressants are effective in reducing the frequency and severity of tension-type headache.

See Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Cluster Headache Algorithm Annotations

71. Patient Meets Criteria for Cluster Headache?

There is no more severe pain than that sustained by a cluster headache sufferer. This headache is often termed "suicide headache." Cluster headache is characterized by repeated short-lasting but excruciating intense attacks of strictly unilateral peri-orbital pain associated with local autonomic symptoms or signs. The most striking feature of cluster headache is the unmistakable circadian and circannual periodicity. Many patients typically suffer daily (or nightly) from one or more attacks over a period of weeks or months.

Evidence supporting this recommendation is of classes: A, R

75. Acute Treatment

Oxygen inhalation is highly effective when delivered at the beginning of an attack with a non-rebreathing facial mask (7-15L/min). Most patients will obtain relief within 15 minutes.

Acute drugs may be difficult to obtain in adequate quantity.

Subcutaneous sumatriptan is the most effective self-administered medication for the relief of cluster headaches. Sumatriptan is not effective when used before the actual attack nor is it useful as a prophylactic medication.

DHE provides prompt and effective relief from cluster headaches in 15 minutes but due to the rapid peak intensity and short duration of cluster headaches, DHE may be a less feasible option than sumatriptan.

See Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Evidence supporting this recommendation is of classes: A, R

76. Prophylactic Treatment

Effective prevention cannot be overemphasized in these patients. Maintenance prophylaxis is critically important since cluster headache sufferers typically experience one or more daily (or nightly) attacks for a period of weeks or months. The goal of transitional therapy is to induce rapid suppression of attacks while maintenance therapy is intended to provide sustained suppression over the expected cluster period.

If the patient has intractable headache or is unresponsive to prophylactic treatment, consider referral to a headache specialist.

See Annotation Appendix A, "Drug Treatment Tables" in the original guideline document.

Evidence supporting this recommendation is of classes: A, R

DHE (Dihydroergotamine Mesylate) Algorithm Annotations

83. Metoclopramide 10 mg Intravenous (IV)

Metoclopramide (10 mg) is given either by direct IV injection over 2 to 3 minutes, or infused intravenously in 50 mL of normal saline over 15 minutes. Each dose of metoclopramide should be administered 15 minutes prior to each DHE injection. Although uncommon, acute extrapyramidal side effects such as dystonia, akathisia, and oculogyric crisis may occur after administration of metoclopramide. Benztropine mesylate (Cogentin®) is effective in terminating this unusual adverse event given as a 1-mg injection (IV or intramuscularly [IM]). Often after 5 doses, metoclopramide may be given as needed for nausea.

Evidence supporting this recommendation is of class: A

85. Begin Continuous DHE

Begin DHE 3 mg in 1,000 mL normal saline at 42 mL/hr.

Continue metoclopramide 10 mg IV every 8 hours as needed for nausea.

Side effects:

- If significant nausea occurs at any time, reduce the rate of DHE to 21 to 30 mL/hr.
- If diarrhea occurs, give diphenoxylate with atropine (Lomotil), 1 or 2 tablets, three times daily as needed
- If excessive anxiety, jitteriness (akathisia), or dystonic reaction occurs, give IV benztropine (Cogentin®) 1 mg.

It may be continued up to 7 days. Opioid analgesics should not be used with either protocol since these are likely to prolong the headache via analgesic rebound.

87. DHE Test Dose

A test dose of DHE (0.5 mg) is given either as a direct IV push slowly over 2 to 3 minutes or as an infusion diluted in 50 mL of normal saline over 15 to 30 minutes.

88. Blood Pressure (BP) Stable/No Chest Pain?

DHE is relatively contraindicated if blood pressure is sustained greater than or equal to 165/95. Discontinue DHE if patient develops chest pain.

90. Common Side Effects

The most common side effects include nausea, vomiting, diarrhea, abdominal cramps, and leg pain. These side effects usually resolve by reducing the dose and co-administering metoclopramide as an antiemetic. Diarrhea can be managed with diphenoxylate with atropine (Lomotil®), one or two tablets three times daily or as needed. Although most patients who respond will do so within 48 hours, this protocol may be continued for 3 to 5 days in those patients whose response is suboptimal.

Menstrual-Associated Migraine Algorithm Annotations

101. Menstrual-Associated Migraine

"Menstrual migraine," a term misused by both patients and doctors, lacks precise definition. The literature has proposed that menstrual-only migraine be defined as attacks exclusively starting on day 1 \pm 2 days of the menstrual cycle. The woman should be free from attacks at all other times of the cycle. Many women who don't have attacks exclusively with menses have menstrual-associated migraines.

Evidence supporting this recommendation is of class: R

102. Diagnosis of Menstrual Migraine Confirmed with Menstrual Record?

The provider and patient need to discuss diary documentation. The patient should keep a continuous daily record for at least 2 months to include the following:

- Day/time of headache
- Severity of headache
- Duration
- Onset of menstrual flow

110. Cyclic Prophylaxis

- Nonsteroidal anti-inflammatory drugs (NSAIDs)

Nonsteroidal anti-inflammatory drugs should be considered approaches of first choice in the prophylactic treatment of migraine associated with menses. Conclusion Grade III: See Conclusion Grading Worksheet -- Appendix A -- Annotation #110 [NSAIDs] in the original guideline document).

Naproxen sodium 550 mg twice daily has been used as a preventive agent, although other NSAIDs may also be effective. Typically, the agent is initiated two to three days before anticipated onset of the headache and continued through the at-risk period.

- Triptans
- Ergots

Evidence supporting this recommendation is of classes: A, C, D, R

113. Hormonal Prophylaxis

- Estradiol Patches

Estrogen levels decrease during the late luteal phase of the menstrual cycle, likely triggering migraine. Estrogen replacement prior to menstruation has been used to prevent migraine.

Estradiol patches, 50 to 100 micrograms, are applied 48 hours prior to expected onset of migraine and used for one week.

- Estrogen-Containing Contraceptives

Estrogen-containing contraceptives have a variable effect on migraines, causing worsening of headaches in some patients, improvement of headaches in a small percentage of patients, and no change in migraines in other patients. Guideline developers are not aware of any population-based studies on this topic.

- Gonadotropin-Releasing Hormone (GnRH) Agonists with "add back" therapy

For patients with severe menstrual migraine unrelieved by other therapies, suppression of the menstrual cycle with a gonadotropin-releasing hormone agonist and "add back" therapy may be effective. Lupron Depot 3.75 mg IM is given monthly with "add back" therapy such as 0.1 mg transdermal estradiol patches and oral medroxyprogesterone acetate 2.5 mg daily or micronized progesterone 100 mg daily.

114. Evidence supporting this recommendation is of classes: C, D, R

[Perimenopausal or Menopausal Migraine Algorithm Annotations](#)

117. Perimenopausal or Menopausal with Active Migraine History

Menopause is the permanent cessation of menses.

Perimenopause is the span of time from the reproductive to the post-reproductive interval, as defined in the NGC summary of the Institute for Clinical Improvement's (ICSI's) [Menopause and Hormone Therapy \(HT\): Collaborative Decision-making and Management](#) guideline.

Hormonal therapy may worsen, improve, or leave migraines unchanged.

Evidence supporting this recommendation is of class: A, C, R

125. Hormone Therapy
- Transdermal or oral estrogen
 - Progestin if indicated
 - Estrogen-containing contraceptives

Refer to the NGC summary of the ICSI guideline [Menopause and Hormone Therapy \(HT\): Collaborative Decision-making and Management](#).

Evidence supporting this recommendation is of class: R

126. Successful?

Successful is commonly defined as a 50% reduction in frequency in headache days and/or severity of headaches.

[On Estrogen-Containing Contraceptives or Considering Estrogen-Containing Contraceptives with Migraine Algorithm Annotations](#)

131. On Estrogen-Containing Contraceptives or Considering Estrogen-Containing Contraceptives with Migraine

Migraine patients who do not have absolute contraindications to estrogen-containing contraceptives should consider that estrogen-containing contraceptives may have unpredictable effects on the severity and/or frequency of headaches. In addition, evidence exists that the risk of ischemic stroke increases for migraineurs taking estrogen-containing contraceptives.

Evidence supporting this recommendation is of classes: C, R

133. Evaluate Stroke Risk Factors
- Risk factors for coronary artery disease (CAD)
 - Migraine aura

Women who have migraine with an aura probably have significantly increased ischemic stroke risk if estrogen-containing contraceptives are used. This risk probably increases with age as baseline stroke rates increase, so that the increased risk may be acceptable to the younger patient (e.g. under age 30), but not to the older patient. It is probably too simplistic to say that no patient with migraine with aura should use estrogen-containing contraceptives. The decision should be individualized and should be made with the patient.

It appears reasonable that women who have prolonged migraine auras (certainly those beyond 60 minutes), multiple aura symptoms, or less common aura symptoms (e.g., dysphasia, hemiparesis) should be strongly discouraged from using estrogen-containing contraceptives.

Patients who develop a migraine aura for the first time while using estrogen-containing contraceptives, or whose previous typical migraine aura becomes more prolonged or complex, should discontinue estrogen-containing contraceptives.

Use of oral contraceptives in patients with a history of migraine increases the risk of stroke [Conclusion Grade II: See Conclusion Grading Worksheet - Appendix B - Annotation # 133 (Risk of Stroke) in the original guideline document]

- Women with migraine aura who smoke and are hypertensive further increase their risk. Additional risk is also noted if they are taking estrogen-containing contraceptives.

Evidence supporting this recommendation is of classes: C, R

Migraine Prophylactic Treatment Algorithm Annotations

144. Prophylactic Treatment

- Criteria for Prophylactic Treatment
 - Three or more severe migraine attacks per month that fail to respond adequately to symptomatic therapy.
 - Less frequent but protracted attacks which impair the patient's quality of life.
 - Patient is interested in prophylactic treatment.
- Prophylactic Therapy

Prior to instituting prophylactic therapy for migraine, it is imperative that realistic goals and expectations be established. Patients should have a clear understanding that the goals of preventative therapy are to:

- Decrease migraine attack frequency by more than 50%
- Decrease pain and disability with each individual attack
- Enhance response to acute, specific, anti-migraine therapy

One or more of these goals may be achieved.

- Medications

The choice of prophylactic agent depends upon:

- Potential efficacy
- Side effect profile
- Comorbid conditions
- Medication interactions

Patients should also understand that there is usually a latency of at least 3 to 6 weeks between the initiation of medication and recognizable efficacy. Often, an 8 to 12 week trial is necessary, allowing an adequate period for drug titration to a dosage likely to attain efficacy. It is also not uncommon for initial side effects to subside after continued therapy, and patients should be made aware of this so as to avoid premature discontinuation of a potentially effective medication.

- First-Line Treatment

The choice of prophylactic medication should be individualized according to the side effect profile, the presence of comorbid conditions, and risk of medication interaction. For example, a tricyclic antidepressant may be especially useful with a migraineur with depression, while sodium valproate may be ideal for a patient with epilepsy. See Annotation Appendix B, "Prophylactic Treatment" and Annotation Appendix C, "FDA Risk Factors for Drug Treatment in Pregnant Women" in the original guideline document.

There are additional medications other than the drugs recommended in the table in Annotation Appendix A of the original guideline document, "Drug Treatment Tables," which may be of equal effectiveness. They are not included in the table, however, because of infrequent use by primary care physicians.

Reinforce education and lifestyle management

- 145. See Annotation # 16 in the [Diagnosis Algorithm](#).
- 146. Evidence supporting this recommendation is of classes: A, C
- 147. Other Therapies
- 148. The treatment therapies listed below are in alphabetical order and do not indicate work group preference or scientific support.

- Acupuncture

This therapy has been found to be expensive and of variable availability. Controlled studies specifically applied to migraine have produced mixed findings.

- Biofeedback

Various methods of biofeedback have been used as adjunctive therapy for migraine. This treatment modality should be considered, particularly for pregnant patients and those not easily treated with pharmacological agents. Thermal control is frequently the preferred technique, wherein the patient learns to elevate finger temperature during therapy sessions using a digital temperature reading device.

Biofeedback is time-consuming and requires a commitment on the part of the patient.

Evidence supporting this recommendation is of class: C

- Botulinum Toxin A

There is one placebo-controlled, randomized trial and several observational studies that demonstrate the effectiveness of botulinum toxin A injections for the prophylaxis of migraine headaches. It should be considered when first-line prophylactic agents have failed or are

contraindicated. For best results, therapy should be administered by a provider with experience using botulinum toxin A for headache.

- Butterbur root (*Petasites hybridus*)

An extract from the plant *Petasites hybridus* has been shown to have benefit for migraine prevention. Dosages were from 100 to 150 mg per day in these studies.

Evidence supporting this recommendation is of class: A

- Cognitive Behavioral Therapy

This therapy is based on the premise that anxiety and distress aggravate an evolving migraine, and has the potential for helping the patient recognize maladaptive responses that may trigger a headache.

Evidence supporting this recommendation is of class: R

- Feverfew

This herbal therapy is made from crushed chrysanthemum leaves. 250 micrograms of the active ingredient, parthenolide, is considered necessary for therapeutic effectiveness. Because these are herbal preparations, the quantity of active ingredient varies with the producer.

Evidence supporting this recommendation is of classes: A, M

- Magnesium

Daily oral dosages of 400 to 600 mg of this salt have been shown to be of benefit to migraineurs in European studies.

Evidence supporting this recommendation is of class: A

- Relaxation Training

Relaxation training includes progressive muscular relaxation, breathing exercises, and directed imagery. The goal is to develop long-term skills rather than to treat individual events. Repetitive sessions and practice by the patient increase the successfulness of these therapies in reducing headache frequency.

Evidence supporting this recommendation is of class: A

- Riboflavin

A randomized, placebo-controlled study has found daily supplements of 400 mg moderately effective in reducing the frequency and severity of migraine.

Evidence supporting this recommendation is of class: A

149. Several additional treatment modalities are available. The modalities listed below lack sufficient scientific support to be recommended as therapies of proven value.

- Cervical Manipulation

Previous studies suggested potentially high levels of risk associated with improper application of this modality. Although more recent studies report few complications, the scientific evidence is not convincing. There is well-documented evidence of cerebral infarction and death from cervical manipulation.

Evidence supporting this recommendation is of classes: A, D

- TENS (Transcutaneous Electrical Stimulation) Units

TENS units for migraine or muscle contraction headache have not been found to be more beneficial than placebo when evaluated in a controlled study.

Evidence supporting this recommendation is of class: A

146. Continue Treatment for 6-12 Months, Then Reassess

After 6 to 12 months, a gradual taper is recommended unless headaches become more frequent or more severe.

147. Try Different First-Line Medication or Different Drug of Same Class

Monotherapy is recommended with dose increasing until patient receives benefit, maximum recommended dose is reached, or unacceptable side effects occur. Failure with one medication does not preclude using another from the same class.

150. Try Combination of Beta-Blockers and Tricyclics

A beta-blocker and a tricyclic antidepressant may be more effective and produce fewer side effects in combination than a single drug at a higher dose from either class.

Definitions:

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented

below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for diagnosis and treatment of headache, including a [Main algorithm](#) as well as the following algorithms:

- [Diagnosis](#)
- [Migraine Treatment](#)
- [Tension-Type Headache](#)
- [Cluster Headache](#)
- [DHE \(Dihydroergotamine Mesylate\)](#)
- [Menstrual-Associated Migraine](#)
- [Perimenopausal or Menopausal Migraine](#)
- [On Estrogen-Containing Contraceptives or Considering Estrogen-Containing Contraceptives with Migraine](#)
- [Migraine Prophylactic Treatment](#)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting

these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, evaluation, and management of migraine headaches, leading to the prevention of or reduction in symptoms and improvement in functional status

POTENTIAL HARMS

Side Effects of Medication

Refer to Annotation Appendix A, "Drug Treatment Tables" and Annotation Appendix B, "Prophylactic Treatment," in the original guideline document for a list of side effects of recommended drugs.

Use of drugs for acute treatment of headache for more than 9 days per month is associated with an increased risk of chronic daily headache.

Subgroups Most Likely to be Harmed

Refer to Appendix C in the original guideline document, "Food and Drug Administration (FDA) Risk Factors for Drug Treatment in Pregnant Women" for precautions in pregnant and lactating women.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Nonsteroidal anti-inflammatory drugs: Contraindications include active peptic ulcer disease, renal insufficiency.
- Triptans: Contraindications include uncontrolled hypertension, vasospastic angina, peripheral vascular disease, pregnancy, ischemic cerebrovascular disease, use of other 5-HT agonists or ergotamines if used within 24 hours.
- Dihydroergotamine mesylate (DHE), Ergotamine: Contraindications include pregnancy, ischemic heart disease, vasospastic angina, advanced peripheral vascular disease, ischemic cerebrovascular disease, uncontrolled hypertension, use within 24 hours of receiving any triptan.

Refer to Annotation Appendix A, "Drug Treatment Tables" and Annotation Appendix B, "Prophylactic Treatment" in the original guideline document for a detailed list of contraindications to recommended drugs.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quality Measures

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED NQMC MEASURES

- [Diagnosis and treatment of headache: percentage of migraine sufferers with treatment plans for mild, moderate, and severe headaches.](#)
- [Diagnosis and treatment of headache: percentage of migraine sufferers with documented education.](#)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of headache. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jan. 70 p. [121 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Aug (revised 2006 Jan)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint

Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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GUIDELINE COMMITTEE

Committee on Evidence-Based Practice

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

John Beithon, MD, is a member of the speaker's bureau for GlaxoSmithKline and Pfizer. He jointly owns a large amount of Pfizer stock through converted options.

Frederick Taylor, MD, receives grant support from Allergan, Ortho-McNeil. He is a consultant for AGA Medical and received honoraria from GlaxoSmithKline, Merck, Pfizer, Pri-Med, Allergan, and Astra-Zeneca.

Jerry Swanson, MD, has served as a consultant for AstraZeneca, Winston Laboratories, Pozen, and Pfizer.

Chris Hult, MD is a member of the speaker's bureau for Risperdol and her spouse works with Risperdol.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Diagnosis and treatment of headache. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 68 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Diagnosis and treatment of headache. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2006 Jan. 1 p. Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).
- ICSI pocket guidelines. May 2005 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2005. 404 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

The following is available:

- Headache, diagnosis and treatment. Bloomington (MN): Institute for Clinical Systems Improvement, 2005 Oct. 31 p.

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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